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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,651	08/30/2000	Michael Lassner	MTC 6718	1981

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/651,651

Applicant(s)

LASSNER ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-22,24-43,45-75,79-83,85,87-107 and 109-117 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,10,11,22,26,28,30,32,34,36,38,40-43,45-50,107,111,113,115 and 117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

5-04

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,8,9,12-21,24-25,27,29,31,33,35,37,39,51-75,79-83,85,87-106,109-110,112,114 and 116.

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DETAILED ACTION

Rejection of Claims 6-7 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendments.

Rejection of Claims 46-47 and 49-50 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments.

Rejection of Claim 41 under 35 U.S.C. 102(a) is withdrawn in view of Applicant's amendments.

Claims 2, 23, 44, 76-78, 84, 86, and 108 are canceled. Claims are 1, 3-22, 24-43, 45-75, 79-83, 85, 87-107 and 109-117 pending. Claims 3, 4, 8, 9, 12-21, 24-25, 27, 29, 31, 33, 35, 37, 39, 51-75, 79-83, 85, 87-106, 109-110, 112, 114 and 116 are withdrawn. Claims 1, 5-7, 10, 11, 22, 26, 28, 30, 32, 34, 36, 38, 40-43, 45-50, 107, 111, 113, 115 and 117 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004. Applicant's arguments filed 3/21/2005 have been considered but are not deemed persuasive.

Applicant asserts that each and every embodiment of the invention need not be described and that the specification in Examples 4-6 described insect and plant cells that transformed with vectors that contain the lecithin:cholesterol acyltransferase-like encoding polynucleotides and in Example 9 described transformed plants with increased oil levels (response page 22).

Applicant has defined lecithin:cholesterol acyltransferase-like as including any nucleic acid sequence encoding an amino acid from a plant source which demonstrates the ability to utilize lecithin (phosphatidyl choline) as an acyl donor for acylation of sterols or glycerides to form esters on pages 10-11 of the specification. However, Applicant has shown only the formation of sterol esters in cells transformed with LCAT 3 (i.e. SEQ ID NO: 6) and LCAT 4 (SEQ ID NO: 8).

Applicants fail to describe a representative number of isolated polynucleotides encoding an *Arabidopsis* lecithin:cholesterol acyltransferase-like polypeptide; isolated polynucleotides having at least 80% sequence identity to SEQ ID NO: 4; isolated polynucleotides encoding SEQ ID NO: 5 with at least one conservative amino acid substitution; isolated polynucleotide that hybridizes to SEQ ID NO: 4 under conditions of unspecified stringency and encodes a plant lecithin:cholesterol acyltransferase-like polypeptide. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides encoding an *Arabidopsis* lecithin:cholesterol acyltransferase-like polypeptide; isolated polynucleotides having at least 80% sequence identity to SEQ ID NO: 4; isolated polynucleotides encoding SEQ ID NO:

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5 with at least one conservative amino acid substitution; isolated polynucleotide that hybridizes to SEQ ID NO: 4 under conditions of unspecified stringency and encodes a plant lecithin:cholesterol acyltransferase-like polypeptide.

Claims 1-2, 5, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115 and 117 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 4 encoding a plant lecithin:cholesterol acyltransferase-like polypeptide of SEQ ID NO: 5, recombinant vectors comprising SEQ ID NO: 4, and plants transformed therewith having increased oil content in transformed seeds, does not reasonably provide enablement for any non-exemplified polynucleotide from plants or non-plant sources encoding a lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof; or for non-exemplified polynucleotides which are at least 80% complementary to SEQ ID NO: 4; or for non-exemplified polynucleotides that hybridize to SEQ ID NO: 4 encoding a lecithin:cholesterol acyltransferase-like polypeptide other than SEQ ID NO: 4; or plants transformed with any sequence encoding a lecithin:cholesterol acyltransferase-like polypeptide in sense or antisense orientation producing transformed seeds having an increase in sterol-esters, oil content or sterol content in transformed seeds; or for plants transformed with LCAT2 SEQ ID NO: 4 producing transformed seeds having increased sterol-ester or increased phytosterol content. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004. Applicant's arguments filed 3/21/2005 have been considered but are not deemed persuasive.

Applicant asserts that Applicants have described the isolation and identification of *Arabidopsis* sequences encoding lecithin:cholesterol acyltransferase (response page 24).

Clearly, Applicant has only described the isolation and identification of *Arabidopsis* sequences encoding lecithin:cholesterol acyltransferase-like proteins the definition of which includes sequences encoding lecithin:cholesterol acyltransferase activity. Further, Applicant has not responded to the Examiners assertion that it appears Applicant's elected invention drawn to SEQ ID NO: 4 does not produce phytosterols or esterified sterols when assayed *in vitro*. Only LCAT 4 (SEQ ID NO: 8) showed products of lecithin:cholesterol acyltransferase activity (see page 47 of specification).

Applicant asserts that the fact that LCAT2 (i.e. SEQ ID NO: 4 encoding SEQ ID NO: 5 of the instant claims) did not show increased levels of plant sterols when transformed into *Arabidopsis* is irrelevant (response page 24).

Clearly there was an increase in oils in plants transformed with SEQ ID NO: 4. The claims are drawn to lecithin:cholesterol acyltransferase-like sequences that will result in an increase in oil when transformed into plants and only SEQ ID NO: 4 is enabled to do so.

Applicant has defined lecithin:cholesterol acyltransferase-like as including any nucleic acid sequence encoding an amino acid from a plant source which demonstrates the ability to utilize lecithin (phosphatidyl choline) as an acyl donor for acylation of sterols or glycerides to form esters on pages 10-11 of the specification. However, Applicant has shown only the formation of sterol esters in cells transformed with LCAT 3 (i.e. SEQ ID NO: 6) and LCAT 4 (SEQ ID NO: 8). Applicant has not responded to the enablement art that showed a likely candidate for lecithin:cholesterol acyltransferase showed phospholipase A1 activity when

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transformed into a yeast mutant resulting in the accumulation of triacylglycerol (TAG) and fatty acids (FA) but no increases in sterol-esters (SE). (Noiriel A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764; see Abstract lines 1-7; cloning of LCAT-like cDNAs on page 3753 in column 2; page 37576 column 2 beginning with line 4; and the Discussion beginning on page 3761 to page 3762 column 1 line 4).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified polynucleotide sequences encoding non-exemplified putative lecithin:cholesterol acyltransferase-like polypeptides and fragments thereof, by producing expression vectors to test for activity and product formation and by transforming plants therewith, in order to identify those polynucleotides that when over-expressed or expressed in antisense orientation would produce plants that yield increased phytosterols, increased oil content, or increases in the amount of esterified sterols in their transformed seeds.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

Claims 1, 5-7, 10-11, 22, 26, 28, 30, 32, 34, 36, 38, and 40 remain rejected under 35 U.S.C. 102(a) as being anticipated by Federspiel N. *et al.* Gene F21M11.5 as GenBank Accession Number AC003027 December 30, 1998 in light of The Institute for Genomic Research database annotation for Gene F21M11.5; see attachment. This rejection is maintained

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for the reasons of record set forth in the Official action mailed 12/16/2004. Applicant's arguments filed 3/21/2005 have been considered but are not deemed persuasive.

Applicant asserts that a claim is anticipated only if each and every element of the claim is anticipated in a single art reference and that the Federspiel reference does not contain any annotation of the lecithin:cholesterol acyltransferase coding sequence and since the TIGR database reference contains no date for the entry of the annotation for locus F21M11.5 the activity of the protein encoded by the nucleic acid sequence would not have been known at the filing, the reference should not be considered as an anticipatory prior art reference (response page 25).

With respect to Claims 1, 5-7, 10 and 11, there are limitations in these claims that do not recite that the nucleic acid sequence encodes a lecithin:cholesterol acyltransferase-like protein. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the nucleic acid sequence encodes a lecithin:cholesterol acyltransferase-like protein) are not recited in the rejected claim(s) or are recited in the alternative with non-functional limitations (i.e. in claim 1 "or fragment thereof"). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, Applicant states on page 31, lines 24-30 of the specification, that SEQ ID NO: 4 encoding SEQ ID NO: 5 is GenBank accession AC003027 (December 30, 1998) and the TIGR database teaches that it is a lecithin:cholesterol acyltransferase and thus SEQ ID NO: 5 is inherently described.

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In response to Applicant's assertion that a claim is anticipated only if each and every element of the claim is anticipated in a single art reference See MPEP 2131.01 part III;

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
June 12, 2005

Russell Kallis
RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER